

**REMARKS**

**Status of the Claims**

Claims 16, 18, 31, 34, 36 and 38-45 are currently pending in the application. Claims 16, 18, 31, 34, 36 and 38-45 stand rejected. Claims 16, 18, 31, 36, 39 and 43 have been amended as set forth herein without prejudice or disclaimer. No new matter has been added by way of the present amendments.

Specifically, the amendment to claims 16 and 18 are to remove the phrase “and DNAs which do not serve as templates for subject DNA synthesis or as primers” from the recited Markush Group and to correct misspellings.

The amendment to claim 31 is supported by the specification at, for instance, page 21, lines 14-23 and Example 13, and original claim 16.

The amendment to claim 36 is supported by the specification at, for instance, page 21, lines 14-23 and Example 13, and original claim 18.

The amendment to claim 39 is supported by the specification at, for instance, page 5, line 15 to page 6, line 5 and page 7, line 18 to page 8, line 19.

The amendment to claim 43 is supported by the specification at, for instance, page 21, lines 14-23 and Example 13, and original claim 39.

Reconsideration is respectfully requested.

**Rejections Under 35 U.S.C. § 102(b)**

Claims 16, 18, 40-42 and 45 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Miura et al., EP 0802258 (hereinafter, "Miura et al."). (See, Office Action of October 18, 2006, at page 3, paragraph 6, hereinafter, "Office Action"). Applicants traverse the rejection as set forth herein.

The Examiner states that Miura et al. disclose a DNA synthesis reaction comprising all of the components recited in the rejected claims. As to part 2) of claims 16 and 18, the Examiner states that the reactions disclosed in Miura et al. include DNAs (nucleotides A, G, C and T) that do not serve as templates for subject DNA synthesis or as primers, as recited in part 2) of claims 16 and 18.

Although Applicants do not agree that claims 16 and 18 are anticipated by the disclosure of Miura et al., to expedite prosecution, claims 16 and 18 have been amended herein, without prejudice or disclaimer, to remove the phrase “and DNAs which do not serve as templates for subject DNA synthesis or as primers,” from the Markush Group of water-soluble acidic macromolecular substances. The Examiner states that Miura et al. disclose a DNA polymerase, DNA which does not serve as a template for DNA synthesis and components necessary for DNA synthesis. However, Miura et al. do not disclose any of the remaining acidic water-soluble macromolecular substances recited in the Markush group of part 2) of claims 16 and 18. Thus, the disclosure of Miura et al. cannot anticipate the presently claimed invention, at least as recited in amended claims 16 and 18. “A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” (*See, Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 U.S.P.Q.2d 1051, 1053 (Fed. Cir. 1987)).

Dependent claims 40-42 and 45 are not anticipated as, *inter alia*, depending from a non-anticipated base claims, amended claims 16 and 18.

Reconsideration and withdrawal of the anticipation rejection of claims 16, 18, 40-42 and 45 are respectfully requested.

### **Rejections Under 35 U.S.C. § 103(a)**

#### Miura et al. & Strategene Catalog (1988)

Claims 31, 34, 36 and 38 stand rejected under 35 U.S.C. § 103(a) as being unpatentable as obvious over Miura et al. and page 39 of the Strategene Catalog (1988, hereinafter "the Stratagene Catalog"). (*See, Office Action, at page 4, paragraph 9*). Applicants traverse the rejection as hereinafter set forth.

The Examiner states that although Miura et al. do not disclose kits, Miura et al. disclose all other limitations of the claims, including the thermostable DNA polymerase of claims 34 and 36. Furthermore, the Examiner states that the Strategene Catalog of 1988 discloses kits and provides motivation to assemble kits.

However, as stated above, with respect to the anticipation rejections, Applicants have amended claims 16 and 18 herein without prejudice or disclaimer to remove the phrase "and DNAs which do not serve as templates for subject DNA synthesis or as primers," from the Markush Group of water-soluble acidic macromolecular substances. Likewise, claims 31 and 35 have been amended herein, without prejudice or disclaimer, to recite in parts 1), 2) and 3) similar components as recited in amended claims 16 and 18. Amended claims 31 and 35 also do not list DNAs which do not serve as templates for DNA synthesis or primers in the Markush Group of part 2).

The Examiner states that Miura et al. disclose a DNA polymerase, DNA that does not serve as a template for DNA synthesis and components necessary for DNA synthesis. However, Miura et al. do not disclose or suggest any of the remaining water-soluble acidic macromolecular substances recited in the Markush group of part 2) of amended claims 31 and 36. The disclosure of Stratagene Catalog also does not provide disclosure or suggestion of the substances listed in part 2) of claims 31 and 36. Thus, since the disclosure of Miura et al. do not disclose or suggest all limitations of the presently amended claims, Miura et al., cannot make obvious the presently claimed invention, at least as recited in amended claims 31 and 36. (*See, In re Vaeck*, 947 F.2d 488, 20 U.S.P.Q.2d 1438 (Fed. Cir. 1991)).

Dependent claims 34 and 38 are also believed to be non-obvious since they depend from amended claims 31 and 36. That is, as dependent claims, claims 34 and 38 incorporate all of the claim limitations of the amended independent claims from which they depend. Thus, dependent claims 34 and 38 also recite limitations not disclosed or suggested by either disclosures cited by the Examiner.

Reconsideration and withdrawal of the obviousness rejection of claims 31, 34, 36 and 38 are respectfully requested.

Demeke et al., Biotechniques, 12:332 and 334, 1992 & Barnes, U.S Patent No. 5,436,149

Claim 39 stands rejected under 35 U.S.C. § 103(a) as being unpatentable as obvious over Demeke et al., *Biotechniques*, 12:332 and 334, 1992 (hereinafter, "Demeke et al.") and Barnes,

U.S Patent No. 5,436,149 (hereinafter, "Barnes"). (See, Office Action, at page 4, paragraph 9). Applicants traverse the rejection as hereinafter set forth.

The Examiner states that although Demeke et al. do not disclose a DNA polymerase having 3' to 5' exonuclease activity, Barnes discloses a composition comprising two DNA polymerases, one of which has such activity. Thus, in combination, the Examiner states that the two references make obvious the subject matter of claim 39 since Barnes states that such DNA polymerase activity is useful for amplifying long DNA targets.

Applicants argue that Demeke et al. actually strongly teach away from the presently claimed invention. Claim 39 has been amended herein, without prejudice or disclaimer, to recite, in part, that the water-soluble acidic macromolecular molecules recited in the Markush Group of part (b) enhance DNA synthesis. As was discussed in our Response of October 13, 2005, at pages 10-11, Demeke et al. do not teach the use of the recited reaction enhancers to improve DNA synthesis reactions. To the contrary, Demeke et al. teach that addition of such molecules decreases DNA synthesis or act as inhibitors of DNA synthesis. Thus, Demeke et al. teach away from the present invention and **would not provide any motivation** for one of ordinary skill in the art to combine Demeke et al. with any other reference for the purpose of enhancing DNA synthesis. A reference which leads one of ordinary skill in the art away from the claimed invention cannot render it unpatentably obvious. (See, *Dow Chem. Co. v. American Cyanamid Co.* 816 F2d 617, (CAFC 1987)). In determining the scope and content of the prior art, and determining whether the prior art suggested the claimed invention, the references "must be read as a whole and consideration must be given where the references diverge and teach away from the claimed invention." (See, *Akzo N.V. v. United States Int'l Trade Comm'n*, 1 U.S.P.Q.2d 1241, 1246 (Fed. Cir. 1986); *In re Fine*, 5 U.S.P.Q.2d 1596, 1598-99 (Fed. Cir. 1988)). Therefore, Demeke et al. and Barnes cannot render claim 39 *prima facie* obvious under 35 U.S.C. § 103(a).

Furthermore, it is highlighted that Barnes is directed to solving the problem of amplifying longer DNA targets as compared to conventional DNA amplification applications. That is, to attain this object, Barnes use a composition comprising DNA polymerase having 3'  $\rightarrow$  5' exonuclease activity and DNA polymerase not having 3'  $\rightarrow$  5' exonuclease activity. However, the object of Barnes cannot be attained if the Barnes reaction composition is combined with that

of Demeke et al. Demeke et al. disclose or suggest that dextran sulfate and gum ghatti inhibit DNA polymerases that do not have the 3' → 5' exonuclease activity. Thus, according to the teaching of Demeke et al., one of ordinary skill in the art would not combine the disclosures of Demeke et al. and Barnes et al. to obtain the presently claimed invention according to amended claim 39 because Demeke et al. discloses or suggests such compounds as recited in part (b) of claim 39 would inhibit DNA amplification, and not enhance DNA amplification.

Reconsideration and withdrawal of the obviousness rejection of claim 39 are respectfully requested.

Tasa et al., *Meth. Mol. Cell. Biol.*, 5:122-124, 1995 & Barnes

Claim 39 stands rejected under 35 U.S.C. § 103(a) as being unpatentable as obvious over Tasa et al., *Meth. Mol. Cell. Biol.*, 5:122-124, 1995 (hereinafter, "Tasa et al.") and Barnes. (See, Office Action, at page 5, paragraph 10). Applicants traverse the rejection as hereinafter set forth.

The Examiner states that although Tasa et al. do not disclose a DNA polymerase having 3' to 5' exonuclease activity, Barnes discloses a composition comprising two DNA polymerases, one of which has such activity. Thus, in combination, the Examiner states that the two references make obvious the subject matter of claim 39 since Barnes states that such DNA polymerase activity is useful for amplifying long DNA targets.

Specifically, the Examiner alleges that it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to have used two polymerases with different 3'-5' exonuclease activities of Barnes in the composition of Tasa et al. (see Office Action at page 8). However, neither Barnes nor Tasa et al. teach all the elements of claim 39 as amended, and discussed above, with respect to the obviousness rejection of claim 39 over the disclosures of Demeke et al. and Barnes. For instance, Tasa et al. report that heparin has an inhibitory effect on DNA synthesis reactions. Thus, Tasa et al. do not teach or recite the heparin as an enhancer of DNA synthesis reactions. One of ordinary skill in the art would not be motivated to combine Tasa et al. with Barnes et al. to arrive at a DNA synthesis reaction with an enhancer selected from a group including heparin. As mentioned above, a reference which leads one of ordinary

skill in the art away from the claimed invention cannot render it unpatentably obvious. (*Dow Chem. Co.* at 617.)

Reconsideration and withdrawal of the obviousness rejection of claim 39 are respectfully requested.

Demeke et al. & Barnes & Strategene Catalog

Claims 43 and 44 stand rejected under 35 U.S.C. § 103(a) as being unpatentable as obvious over Demeke et al. and Barnes, and further in view of the Strategene Catalog. (See, Office Action, at page 6, paragraph 12). Applicants traverse the rejection as hereinafter set forth.

The Examiner states that although Demeke et al. and Barnes disclose the reaction composition of claim 39, they do not disclose the idea of placing such reagents in kits. However, the Examiner states that the Stratagene Catalog discloses kits and provides a general motivation for placing reagents for conducting a reaction in a kit.

However, as already discussed, above, with respect to the rejection of claim 39 as being obvious in light of the combination of disclosures of Demeke et al. and Barnes, and/or Tasa et al. and Barnes, the Examiner has failed to establish a *prima facie* case of obviousness at least with respect to amended claim 43.

It is noted that claim 43 has been amended herein, without prejudice or disclaimer, to recite similar limitations as recited in claim 39, including the limitation directed at clarifying that the reaction is enhanced by addition of the acidic water-soluble acidic macromolecular substances listed in the Markush Group of part (b) of claim 43.

Thus, for the same reasons as presented above, with respect to the obviousness rejection of claim 39, the same cited references cannot make obvious claim 43, and claim 44 depending therefrom. That is, the disclosure of Demeke et al. teaches away from combining the references in any fashion to arrive at the presently claimed invention.

For the same reasons as already discussed above, it is believed that the Examiner has failed to establish a *prima facie* case of obviousness at least with respect to amended claim 43 because a reference which leads one of ordinary skill in the art away from the claimed invention cannot render it unpatentably obvious. (*Dow Chem. Co.* at 617.)

Therefore, reconsideration and withdrawal of the obviousness rejection of claims 43 and 44 are respectfully requested.

Tasa et al. & Barnes & Strategene Catalog

Claims 43 and 44 stand rejected under 35 U.S.C. § 103(a) as being unpatentable as obvious over Tasa et al. and Barnes, and further in view of the Strategene Catalog. (See, Office Action, at page 7, paragraph 13). Applicants traverse the rejection as hereinafter set forth.

The Examiner states that although Tasa et al. and Barnes disclose the reaction composition of claim 39, they do not disclose the idea of placing such reagents in kits. However, the Examiner states that the Stratagene Catalog discloses kits and provides a general motivation for placing reagents in a kit for conducting a reaction.

However, as already discussed, above, with respect to the rejection of claim 39 as being obvious in light of the combination of disclosures of Demeke et al. and Barnes, and/or Tasa et al. and Barnes, the Examiner has failed to establish a *prima facie* case of obviousness at least with respect to amended claim 43.

It is noted that claim 43 has been amended herein, without prejudice or disclaimer, to recite similar limitations as recited in claim 39, including the limitation directed as clarifying that the reaction is enhanced by addition of the water-soluble acidic macromolecular substances listed in the Markush Group of part (b) of claim 43.

Thus, for the same reasons as presented above, with respect to the obviousness rejection of claim 39, the same cited references cannot make obvious claim 43, and claim 44 depending therefrom. That is, the disclosure of Tasa et al. teaches away from combining the references in any fashion to arrive at the presently claimed invention.

For the same reasons as already discussed above, it is believed that the Examiner has failed to establish a *prima facie* case of obviousness at least with respect to amended claim 43 because a reference which leads one of ordinary skill in the art away from the claimed invention cannot render it unpatentably obvious. (*Dow Chem. Co.* at 617.)

Therefore, reconsideration and withdrawal of the obviousness rejection of claims 43 and 44 are respectfully requested.

## **Rejections Under the Obviousness-Type Double Patenting Doctrine**

### Uemori et al., U.S. Patent No. 6,673,578

Claims 16, 18 and 39 stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 7 of Uemori et al., U.S. Patent No. 6,673,578, (hereinafter referred to as "Uemori et al."). (*See*, Office Action, at page 8, paragraph 15). The Examiner states that claim 7 recites a species of the genus encompassed by claims 16, 18 and 39. Applicants submit herewith a Terminal Disclaimer with respect to Uemori et al. thus obviating the double-patenting rejection.

### U.S. Patent Application Serial No. 10/435,633

Claims 16, 18, 31, 36, 39 and 43 stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 10-17 of U.S. Patent Application Serial No. 10/435,633 (hereinafter referred to as "the '633 application"). (*See*, Office Action, at page 10, paragraph 16). Applicants note that the '633 application has been permitted to become abandoned. As such, this rejection is moot.

**CONCLUSION**

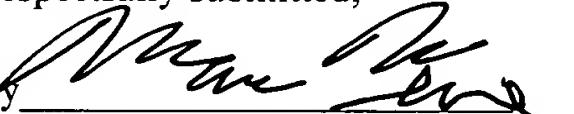
In view of the above amendment, applicant believes the pending application is in condition for allowance.

If the Examiner has any questions or comments, please contact Thomas J. Siepmann, Ph.D., Registration No 57,374, at the offices of Birch, Stewart, Kolasch & Birch, LLP.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to our Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. § 1.16 or under § 1.17; particularly, extension of time fees.

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Respectfully submitted,

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Attachments: Terminal Disclaimer Under 37 C.F.R. § 1.321 over USPN 6,673,578

